

## **PROJECT NARRATIVE**

Current research lacks data regarding “what it takes” to install evidence-based practices (EBPs) into usual care settings, leading to costly public health consequences including wasted efforts and resources on failed implementation attempts and a lack of availability of the most beneficial services to clients. Attempts to examine implementation outcomes and develop implementation interventions are hindered by the absence of tools to measure key processes and stages of implementation across EBPs. This project aims to address this deficit by extending a measure of implementation process to three EBPs in child and family mental health service sectors and to advance the abilities of researchers, developers, and end users to support more successful implementation efforts in real-world settings.

## PROJECT SUMMARY

Over the last decade, there has been an increased effort to implement evidence-based practices (EBPs) into real-world community settings. Accordingly, researchers have sought to understand what steps in the implementation process are essential to effectively transport EBPs to a diverse range of settings, and how to best measure if these steps have occurred well. This proposal maps onto NIH PAR-10-038 by targeting the “development of outcome measures and suitable methodologies for dissemination and implementation approaches that accurately assess the success of an approach to move evidence into practice.” The Stages of Implementation Completion (SIC) is an 8-stage measure that was developed to evaluate the implementation of the Multidimensional Treatment Foster Care (MTFC) model. Each of the stages maps onto the three phases of implementation: pre-implementation, implementation, and sustainability. The SIC measures adopting sites’ implementation performance, as indicated by activity completion and duration, in each of the implementation stages. Early stage implementation performance (i.e., pre-implementation) has been shown to predict successful implementation outcomes for MTFC. In the proposed project, the SIC will be adapted and extended to three new EBPs serving children and families with mental health problems, Multisystemic Therapy, Multidimensional Family Therapy, and a computer-assisted version of Coping Cat, through collaborations with each of the EBP developers. Both retrospective data (from previous site implementation efforts) and prospective data (from newly adopting sites) will be analyzed. The influence of pre-implementation performance on implementation outcomes will be examined (Aim1). *In addition, mixed method procedures will focus on increasing understanding of the underlying processes that lead to implementation success or failure in order to determine if the SIC can provide early detection of sites’ likelihood of success (Aim 2).* Study activities also will include cost mapping of SIC stages and an examination of the relationship between implementation costs and performance (Aim 3). This project, therefore, fills a void in the field of implementation science by addressing the measurement gap in both the implementation process and the associated costs. In collaboration with an Advisory Board comprised of child mental health implementation science experts *and end users*, study outcomes, including the key elements of implementation and associated costs, will be disseminated to the participating EBPs and to the broader field to inform decision makers. The development of a tool that predicts implementation outcomes *by assessing implementation performance* will help identify areas in need of intervention (e.g., through additional support/consultation). Further, the ability to reliably measure implementation processes will facilitate future evaluations of implementation strategies. The overarching goal of this project is to provide tools that will help increase the uptake of EBPs in communities, thereby increasing the availability of services to youth and decreasing wasted resources from failed implementation efforts.

## SPECIFIC AIMS

This proposal maps onto PAR-10-038 by targeting the “development of outcome measures and suitable methodologies for dissemination and implementation approaches that accurately assess the success of an approach to move evidence into practice.” Although many evidence-based practices (EBPs) have been developed, large knowledge gaps remain regarding how to routinely move EBPs into usual care.<sup>1</sup> Little is known about the key processes and steps necessary for successful implementation and how to measure if they have occurred well.<sup>2</sup> There is limited knowledge of what steps are most challenging and costly to complete or those that contribute to the decision to cease implementation. The lack of understanding of “what it takes” to install EBPs has costly public health consequences including limited availability of the most beneficial services, wasted efforts and resources on failed implementation attempts, and the potential for engendering reluctance to adopt new EBPs after failed attempts.

Efforts to examine implementation outcomes are hindered by the lack of available tools to measure the key processes and stages of implementation.<sup>3</sup> For example, no method exists to measure or predict what early implementation activities are necessary for successful program start-up. There also is no method for estimating the costs and resources necessary to complete implementation over and above the cost of the EBP itself,<sup>4</sup> limiting the accuracy of fiscal decision making about total implementation costs. These limitations impede the ability to develop interventions/strategies to enhance and support successful real-world implementation efforts.

This proposal examines the potential of one measure to close this gap by evaluating the implementation processes and associated costs for EBPs being implemented in the real-world. The Stages of Implementation Completion (SIC)<sup>5</sup> is an 8-stage tool developed in a trial comparing two implementation strategies for Multidimensional Treatment Foster Care (MTFC),<sup>6</sup> an EBP for youth with serious behavioral problems. Though limited to MTFC thus far, the SIC has shown promise in predicting both successful and failed implementation. Items delineate the date that a site completes key activities, yielding an assessment of duration (time to complete a stage) and proportion (number of critical stage activities completed). Both duration and proportion during the pre-implementation phase (Stages 1-3) have been shown to predict program start-up of MTFC.<sup>7</sup>

We propose to extend the SIC beyond MTFC to three EBPs that operate in various child service sectors: Multisystemic Therapy in juvenile justice (MST),<sup>8</sup> Multidimensional Family Therapy in substance abuse (MDFT),<sup>9</sup> and a computer-assisted version of Coping Cat (CC)<sup>10</sup> in schools.<sup>11</sup> *Both successful and failed* implementation attempts will be scrutinized using a mixed method design. Stage costs will be measured and examined in relation to implementation outcomes. Progress will be presented to an Advisory Board of implementation experts *and end-users* to obtain feedback, generate hypotheses, and advance the work.

**AIM 1: EXTENSION THROUGH RETROSPECTIVE AND PROSPECTIVE ANALYSIS.** Initial collaboration with EBP developers will be conducted: (a) SIC stages will be populated with *universal and unique* activities that define implementation for each EBP (adaptation). (b) Retrospective data will be coded to evaluate if the EBP-adapted SIC accurately identified implementation processes during previous implementation attempts ( $n = 15/\text{EBP}$ ). Further refinements and modifications to the EBP specific SIC will be made and 15 more sites will be coded retrospectively. (c) Prospective data will be collected from consecutive newly adopting sites ( $\geq 15/\text{EBP}$ ) of the EBPs over 3 years. (d) Analyses will evaluate if site performance predicts program start-up and achievement of competency, and the general operating characteristics of the EBP-adapted SICs.

**AIM 2: UNPACKING FAILED IMPLEMENTATION: EARLY DETECTION OF POTENTIAL FAILURE BY INCREASING UNDERSTANDING OF UNDERLYING SIC MECHANISMS:** (a) Interviews with decision makers from *successful and failed* prospective sites will be conducted to assess perceived *contexts, facilitators, and barriers* to completing implementation. (b) Qualitative findings will be matched with SIC data to assess how performance, as measured by the SIC, compares to the challenges *and behaviors* identified by the sites. The coherence of this information will be discussed with the Advisory Board to aid in the analyses of site perceptions compared to outcomes on the SIC *and to inform understanding of the underlying mechanisms assessed by SIC scores.*

**AIM 3: COSTS BY STAGE AND IMPLEMENTATION OUTCOMES.** Using the SIC as a map of implementation activities, cost data per implementation stage (fees, person hours, salaries, materials) will be collected for each prospective site to examine the impact of SIC proportion and duration on costs. Results will be framed as estimates of the opportunity cost of implementing a new EBP, providing a tool for policy makers to estimate implementation costs and to inform decision-making regarding the adoption of new EBPs.

### GLOSSARY OF TERMS IN APPLICATION

**Practice:** A given specific EBP.

**Site:** Newly adopting programs for each EBP.

**Phases:** Pre-Implementation, Implementation, and Sustainability

**Stages:** The 8 Stages of Implementation on the SIC ranging from Engagement to Competency.

**Universal Items:** Implementation activities identified on the SIC that are common across the EBPs.

**Unique Items:** Implementation activities identified on the EBP-specific SIC that are unique to that EBP.

**Retrospective:** Data from sites that previously adopted the respective EBP prior to project.

**Prospective:** Data from sites that attempt to implement the EBP during the grant period.

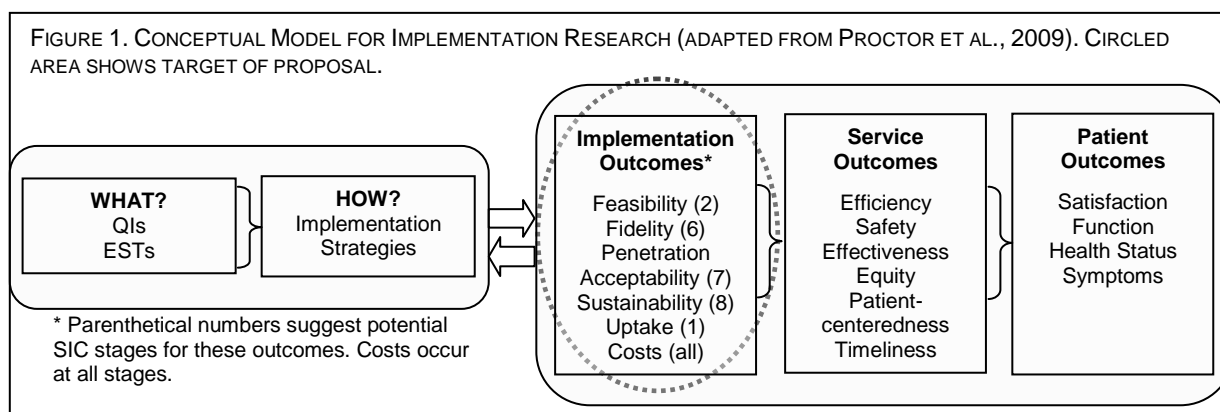
## RESEARCH STRATEGY

### SIGNIFICANCE

With the increased focus and effort to implement evidence-based practices (EBPs) in real-world community settings<sup>12</sup> comes recognition of the complexity of the task, which involves planning, training, quality assurance, and interactions among developers and system leaders, front line staff, and consumers.<sup>1</sup> It is generally thought that it takes a site a minimum of two years to complete the implementation process<sup>13</sup> and that achievement is strongly influenced by the success of the implementation methods.<sup>14</sup> However, little is known about which aspects of these methods are most important for successful implementation.<sup>15</sup> Recently, there has been increased focus on attempting to understand what steps in the implementation process are essential to effectively transport EBPs, and how to best measure if these steps have occurred well.<sup>2,16</sup>

There is consensus that implementation is likely a recursive process with well-defined stages that are not necessarily linear and that impact each other in complex ways.<sup>13,17</sup> A treatment developer or purveyor typically assists programs in navigating their way through each of the implementation stages in an effort to ensure that program elements are delivered in the manner intended. Researchers have called for the measurement of the key processes and stages of adopting an EBP, and the assessment of the fidelity of implementation methods.<sup>18,19</sup> Currently, there are no tools available to accurately measure these stages in a standardized way across EBPs or implementation strategies. As shown in Figure 1,<sup>18</sup> implementation research includes three distinct levels of evaluation including patient, service, and implementation outcomes. Until recently, implementation outcomes were grouped with service outcomes. Leading services researchers, however, have noted the need for a model, like the one provided in Figure 1, that links key implementation stages and outcomes to service and patient outcomes.<sup>20,21</sup> To date, limited tools are available to inform distinctions between these key levels of outcomes, thus limiting the evaluation of these discrete processes. In the current

proposal we seek to narrow this gap by focusing on further development of a measure to assess the process of attaining targets such as those outlined in



the dotted circle. For illustrative purposes, the proposed stage of implementation (described in detail below) that targets each of these outcomes is noted in parentheses.

### CONSIDERATIONS FOR MEASURING IMPLEMENTATION

**PROGRESSION AND TIMING.** Given the non-linear yet staged progression of implementation, the measurement of this process must be flexible enough to capture potential variations. Having a well-defined system of implementation and knowledge about the typical successful progression through the stages could increase the likelihood that a purveyor could provide sites with information in the early stages that will help to support their success in later stages<sup>15</sup> in order to help realistically assess and calibrate their efforts either to proceed, or reconsider whether or not their current implementation plan remains viable. Ideally, such a measure could indicate when agencies are starting to falter or are on an unsuccessful path. Determining when specific barriers hinder successful outcomes is crucial for understanding the implementation process. It would be useful to have early signals that such barriers are on the horizon, and to know what distinguishes when these barriers are significant enough to prevent moving forward (e.g., site and/or fiscal considerations).

**LEARNING FROM FAILURES AND SUCCESS.** Although organizational factors such as climate and culture have repeatedly demonstrated influence on successful implementation,<sup>22</sup> less is known about when failures occur in the implementation process and what the site's perceptions are as to why these failures occurred. Much can be learned from sites that initiate the implementation of an EBP and then fail to reach milestones such as start-up or sustainability<sup>23</sup> *in addition to those that are successful*. Until recently, studies recruited sites retrospectively<sup>18</sup> or have used recruitment designs where EBP champions recruited sites to implement,<sup>14</sup> therefore not reflecting real-world conditions in which sites often initiate the process. In the proposed work we

use a more naturally occurring design where sites are not recruited to implement an EBP, but rather self-select to adopt a practice. This allows for prospective observation of the specific barriers that are perceived by sites as insurmountable at particular stages in the implementation process, *and the differences between sites that are and are not able to overcome them*. We propose to determine if barriers that result in failure can be detected using a standardized measure.

**UNDERSTANDING THE COSTS OF IMPLEMENTATION AND WHEN THEY ACCRUE.** Ritzwoller and colleagues<sup>4</sup> argued for the need for standardized methods of analysis of cost data for behavioral medicine implementation and suggested that this gap in knowledge might play a key role in why new interventions fail to translate from research to practice. Understanding cost is complex and difficult to estimate partly because such estimations depend on what phase of implementation the site is engaged.<sup>24</sup> Related and important to communities, is what specific activities in the implementation process are necessary (versus optional) for program success, and what resources are required to complete them. Although leading theories and frameworks include conceptualization of implementation costs as an important factor (e.g., Figure 1), such costs are an understudied aspect of implementation science,<sup>25</sup> particularly as they relate to specific implementation stages. In the proposed work we will evaluate a standardized method for estimating implementation costs per stage that has the potential to generalize across EBPs and sites. This could be of high value for decision makers who are responsible for determining if they can afford to adopt new practices; some decision makers might underestimate the resources needed for implementation while others might over-estimate the needed resources and limit themselves from adopting practices that could be beneficial to their communities.

### **THE STAGES OF IMPLEMENTATION COMPLETION (SIC)**

The SIC is an 8-stage assessment tool developed as part of a large-scale randomized implementation trial.<sup>5</sup> The trial contrasted two methods of implementing an EBP for youth with serious behavioral problems in the juvenile justice and child welfare systems, Multidimensional Treatment Foster Care (MTFC),<sup>6</sup> in 53 sites in California and Ohio. The goal was to measure a site's progress toward successful implementation of MTFC when the implementation method was either individualized (as usual; IND) or part of a peer-networking Community Development Team (CDT). As shown in Table 1, the SIC has 8 stages with sub-activities within each stage. The stages range from Engagement with the developers to practitioner Competency and map onto three well-accepted phases of implementation (Pre-Implementation, Implementation, Sustainability).<sup>2</sup> These stages also map onto the distinct implementation outcomes presented in Figure 1.

**MEASURING MULTIPLE LEVELS.** One of the complexities of implementation is that different agents at various levels are involved over time (Table 1). Initially, the county system leaders (e.g., juvenile justice, mental health, school) are involved in the decision of whether or not to adopt an EBP, and they often assess implementation feasibility. Over time, the key players in the process shift from system leaders to agency leaders and practitioners, and clients receiving services. A measure of implementation must incorporate data from these multiple levels if it is to accurately capture the complexity at various points in the process.

**SIC SCORES.** Two scores are calculated for each SIC stage. First, the amount of time that a site spends in a stage is calculated by date of entry through date of final activity completed (i.e., Duration Score). Because the implementation process is nonlinear, the Duration Score takes into account that activities might not be completed sequentially within a stage. Second, the percentage of activities completed within a stage is calculated (i.e., Proportion Score). A site might complete a stage quickly, but not all of the sub-activities within that stage. Including both the Duration and Proportion Scores allows for an evaluation of which of these (and the interaction) is most important for successful implementation, and if these findings differ by stage.

**PREDICTIVE ABILITY OF SCORES.** Saldana, Chamberlain, Wang, & Brown<sup>7</sup> found that SIC scores predicted variations in implementation behavior for sites attempting to adopt the MTFC model. Based on stage Proportion and Duration Scores, sites were accurately identified (i.e., face validity) through agglomerative hierarchical cluster analyses. Employing Cox proportional hazard models, cluster membership then was used to predict successful MTFC start-up. Successful program start-up was predicted by site performance, as measured by the SIC in the first three stages (i.e., predictive validity). Findings suggested that sites that completed implementation activities thoroughly (high proportion) but relatively rapidly (duration) were most likely to initiate service. That is, those sites that took longer to complete each stage and completed fewer activities had a significantly lower hazard of having their first placement within the study period (HR = 0.190,  $p = .01$ ) than rapid and thorough completers. Importantly, implementation condition did not significantly contribute to this model ( $p = .33$ ), suggesting that prediction was not attributable to implementation strategy.

**MAPPING COST BY STAGE.** Another analysis from the same trial<sup>26</sup> demonstrated that the SIC could serve as a map for costing implementation procedures. Procedures included calculations of fees, expenses, and person hours necessary to complete each Stage. Differences in cost structures (i.e., the when and how much

for resource allocation) were identified between the implementation conditions (IND vs CDT) despite using the same intervention model (i.e., MTFC). Differences in costs occurred primarily during the pre-implementation phase. Patterns of resource allocation were identified and showed that although some stages were less expensive for one strategy than the other (e.g., Stage 3 IND implementation = \$2,500; CDT implementation = \$8,700), the less expensive strategy might require more person hours or effort (e.g., Stage 3 IND implementation = 206 hours; CDT implementation = 154 hours). Such information is critical for decision makers when determining resource allocation and viability of the implementation strategy.

**PROPOSED ADAPTATIONS OF THE SIC.** Similar to the core components proposed by Blasé and Fixsen<sup>21</sup> as being essential for successful implementation, each of the 8 main stages describes a key milestone that the developers of the three participating EBPs have agreed is necessary for successful implementation. We propose to adapt activities within each stage to target the specific tasks necessary to complete implementation.

TABLE 1. ACTIVITIES AND THE 8 SIC STAGES FOR INDIVIDUAL (IND) OR COMMUNITY DEVELOPMENT TEAM (CDT) IMPLEMENTATION OF MTFC. STAGES LIE WITHIN THE PHASES OF IMPLEMENTATION: PRE-IMPLEMENTATION (PRE-IMP), IMPLEMENTATION (IMP), AND SUSTAINABILITY (SUS).			
Phase	Stage	Activity	Agent Involved
Pre-imp	Stage 1: Engagement	Date site informed services/program available (not scored) Date of interest indicated Date agreed to consider implementation	System Leader
Pre-imp	Stage 2: Consideration of Feasibility	Date of response to first planning contact Date of first CDT meeting/IND Feasibility Assessment Date feasibility questionnaire completed	System Leader, Agency
Pre-imp	Stage 3: Readiness Planning	Date of cost/funding plan review Date of staff sequence, timeline, hire plan review Date of Foster Parent recruitment review Date of referral criteria review Date of communication plan review Date of CDT Meeting #2/IND Stakeholder meeting Date written implementation plan completed Date MTFC Service Provider Selected	System Leader, Agency
Imp	Stage 4: Staff Hired & Trained	Date agency checklist completed Date 1 <sup>st</sup> staff hired Date Program Supervisor trained Date clinical training held Date Foster Parent training held Date Expert Consultant assigned to site	Agency, Practitioner
Imp	Stage 5: Adherence Monitoring processes in place	Date Parent Daily Report training held (fidelity measure) Date of 1 <sup>st</sup> program administrator call	Agency, Practitioner
Imp	Stage 6: Services and Consultation Begin	Date of first placement Date of first consult call Date of first clinical meeting video received Date of first foster parent meeting video received	Practitioner, Child/Family
Imp	Stage 7: Ongoing services, consultation, fidelity monitoring and feedback	Dates of site visits (3) Date of implementation review (3) Date of final program assessment	Practitioner, Child/Family
Sus	Stage 8: Competency	Date of certification application Date certified	System Leader, Agency, Practitioner

Some activities are expected to vary by EBP while others are expected to be common/universal such as fidelity monitoring. There is evidence from our previous work that the decision to implement a new practice is largely based on the community need to serve a particular population,<sup>27</sup> and this perception is likely influenced by what service sector is accessing the population. Thus, it is possible that implementation activities, including early implementation decision-making, differ across service sectors. This study will sample EBPs in three service sectors to build hypotheses about the differences in implementation processes between sectors.

**POTENTIAL IMPACT TO THE FIELD.** *Described previously, there is a lack of standardized measurement of implementation process, milestones, and costs. This gap impedes efforts to help inform real world implementation efforts for both researchers and adopters of EBPs. Measures such as the SIC that can increase the understanding of implementation processes that relate to the successful adoption of EBPs are needed. Such measures have the potential to contribute to theoretical frameworks that form the basis for the development of interventions to improve implementation outcomes for sites at-risk for unsuccessful adoption. The goals of this proposed project are to extend the SIC to additional EBPs in three key child and family service systems, to measure meaningful implementation outcomes, and to examine the potential generation of universal items/common elements across EBP implementation strategies. We propose using a mixed methods*

strategy to increase understanding of what the SIC scores represent to end users and to researchers. We also will evaluate a strategy for mapping implementation costs and resource allocation by Stage that could inform the creation of user friendly fiscal plans for implementation efforts.

There has been considerable interest in adapting the SIC for different practices from treatment developers (e.g., SafeCare; see letter) and research groups (e.g., SUD QUERI; see letter). Following presentations at the 2012 D&I conference of both the MTFC-SIC and the associated costing strategy, the investigative team has received multiple requests for consultation on measuring implementation. Further, the National Cancer Institute has included the MTFC-SIC in the Grid-enabled Measures Database (GEM), a consensus initiative on dissemination and implementation measures and methods; the SIC is one of only three included measures of implementation. This level of interest suggests that extending evaluation of the SIC beyond implementation of the MTFC model has the potential to have a significant impact on the field for EBP developers, adopters, and researchers who share an interest in maximizing the potential for successful uptake of EBPs.

### INNOVATION

The proposed work is innovative in three primary ways. First, a measure of the implementation process that has been shown to predict success of one EBP will be generalized to three EBPs in three child public service sectors. Second, the measure will be examined for its potential to predict, during pre-implementation, which sites are likely to succeed or fail, thereby paving the way for the future development of interventions and strategies to prevent failures and increase the likelihood that EBPs will be successfully adopted. Finally, the cost per stage of implementation will be estimated to increase information for policy/decision makers on what resources are needed to plan for, implement, and sustain each of the EBPs being studied (over and above the cost of the practice itself), and how these costs are influenced by implementation performance.

**GENERALIZATION.** Adopters, EBP developers, and researchers could all benefit from having a measure that helps determine early on and throughout the implementation process if sites are doing well, doing poorly, or just “getting by.” For adopters, such information would allow for ongoing progress monitoring and could inform decisions about potential corrections. For developers, being able to see where sites are struggling would allow for the development of strategic methods for improving their support. For researchers, such measures of process are needed to begin testing the efficacy of existing implementation approaches and frameworks.

**PREDICTION.** The expansion of the SIC will allow for the evaluation of site implementation behavior through observation of progress (both time to completion of key tasks and proportion of tasks completed), thereby providing fine-grained data on progress toward the attainment of key implementation objectives (e.g., program start-up; first client served). Such data can serve as “milestone implementation outcomes” in and of themselves. In the proposed study, achievement of these outcomes will be observed within and across the three practices being studied. At each stage, data on time to completion and proportion of tasks completed during previous stages can be used to predict future milestone achievement at later stages (e.g., when full program census is achieved). *This data will be considered in relation to qualitative data collected from end-users to increase understanding of the underlying mechanisms assessed by SIC scores.* This type of fine-grained data will allow for an examination of which implementation activities are crucial for program success and which activities might be encouraged but are not essential.

**COST.** When decision or policy makers consider whether or not to implement a new EBP, they must consider not only the cost of the intervention, but also the cost of implementing the intervention. They must decide preemptively whether or not to invest in a new practice, and additionally, estimate the implementation costs. This can be a daunting task, especially when implementation costs are likely to differ not only across EBPs, but also between different implementation strategies (as shown in the MTFC trial).<sup>26</sup> Such opportunity costs must be considered against the uncertainty of future benefits. Knowing when different types of costs can be expected during the implementation process could prove critical in helping decision makers map out a clear fiscal plan to ensure proper and timely resource allocation. Data on cost per stage could potentially be reassuring for sites and could clarify what resources are needed, decreasing the potential for both under- and overestimation of resource needs. In the proposed study, the SIC stages will serve as a template for mapping implementation costs within stages and will provide cost curves related to implementation behavior (i.e., duration and proportion). For example, if a site has struggled to complete certain implementation activities and is unclear if they should proceed with implementation, knowing the resource allocation necessary to proceed with the next set of implementation activities within the current fiscal year might be beneficial in making this decision. If, for instance, the site has completed all of the “high cost” activities, they may elect to proceed with the implementation and attempt to complete the remaining, less costly implementation activities despite early struggles. The proposed work would allow for the development of a basis for informed decision-making rather than following the assumption that all implementation activity costs are “equal.” In addition, having a

standardized method of assessing implementation costs will allow for future economic evaluations (e.g., cost-effectiveness, cost-offset, cost-benefit) of implementation strategies.

**SUMMARY.** We propose that these three areas of innovation are likely to contribute to filling gaps in knowledge in the field of implementation science. This knowledge will help pave the way for future studies on the development of interventions to improve implementation approaches, ultimately leading to more successful EBP implementations in child public service systems and greater availability of EBPs in usual care settings.

## **APPROACH**

### **PRELIMINARY STUDIES**

#### **MTFC-SIC FOR REAL-WORLD MTFC SITES**

To evaluate the potential of the SIC to be utilized in a non-research context, the MTFC-SIC was examined with real-world, usual implementation MTFC sites. Because the measure was developed as part of a research trial and sites were recruited, we wanted to test the measure with non-study (real-world) sites to ensure that the SIC could be used to adequately measure implementation performance and outcomes outside of the context of a controlled research design. In collaboration with the MTFC purveyor organization (TFCC, Inc.), records from the 75 most recently implemented MTFC sites were examined retrospectively. Using the MTFC-SIC, activity completion dates were recorded for each of these sites. Through this process it was discovered that the SIC was not as useful for sites with existing programs and adding additional MTFC teams to their organization because they did not complete the implementation process as thoroughly as those sites that were newly initiating their first program (due to previously completing the full process with their first program). Therefore, we limited the data to 35 newly adopting sites. We found that outcomes from the MTFC implementation research trial in the 53 California and Ohio sites were replicated. Sites that failed to successfully implement the MTFC program spent significantly more time (76 days) in the pre-implementation phase than sites that were successful. Sites were successfully clustered into groups. These clusters were used in a Cox proportional hazard survival model, and the rate of stage completion in pre-implementation predicted program start-up. Those sites that took longer to complete their pre-implementation stages had a greater risk of discontinuing than those who completed their stages more rapidly (hazard ratio (HR) = 26.50, p-value < 0.002). In addition to demonstrating the reliability of SIC scores in describing implementation performance and outcomes, this preliminary work illustrates the ability for a purveyor to complete the SIC based on retrospective records of usual implementation activities.

#### **MTFC-SIC MEASUREMENT PROPERTIES**

In another set of analyses in preparation for this application, the measurement properties of the MTFC-SIC were evaluated by analytic consultant Chapman (see letter of support). Several challenges for evaluating its psychometric properties were considered. The activity completion dates create two types of items: Proportion items are standard dichotomous items (was the activity completed or not?), and Duration items follow a time-distribution (how long did it take to complete the activity?). The Duration item format presents an obstacle for estimating basic properties like internal consistency. There also are challenges around missing data. With multiple stages, activities in uninitiated stages are considered missing (i.e., ineligible). However, such missing data is not readily accommodated by traditional psychometric models. Likewise, the sample size is modest, and most models require large samples. Finally, the data are nested with activities within stages that are nested within sites. Nesting is important to model but not feasible for many traditional psychometric models.

Given these challenges, the reliability and validity of the MTFC-SIC items<sup>29,30</sup> were evaluated using IRT-based Rasch models.<sup>28</sup> This highly flexible family of models addresses each of the challenges noted above: the “time” distribution, missing data for some activities, modest sample size, and nested data. According to the model, the probability of a site completing an activity is a function of the difficulty of the activity and the implementation level of the site. For example, a site with high adherence would have a high probability of completing a basic activity. Proportion items and Duration items were evaluated using dichotomous and Poisson<sup>29</sup> models<sup>30,31</sup> and their multilevel extensions (HLM).<sup>32</sup>

**DISTRIBUTIONS & TARGETING.** The model provides separate scores for activities (from least to most difficult) and sites (from least to most adherent). As a critical check on validity, the scores estimated by the model for activities and sites should match what experts (i.e., developers/purveyors) know about the activities and sites. This was found to be true, with experts validating the ordering of both activities and sites. Also, the activities and sites should not be homogenous, which would limit the measure’s utility. There was good heterogeneity, with activity and site distributions covering a relatively wide range ( $\approx 4$  logits). Finally, the activities should be appropriate for the sites, with no evidence of floor effects or ceiling effects. This too was supported. This demonstrates that the SIC measurement approach can be validly used for MTFC, increasing the odds of successfully extending the approach to other EBPs.



**RELIABILITY.** The Rasch model provides two types of reliability statistics. The first, “separation,” indicates the number of different groups of sites (and activities) that can be distinguished in the data. A larger number is better, and the number must fit the use of the instrument. The results indicated that 2-3 different levels of activities and 2 different levels of sites were discriminated for both Proportion items and Duration items. These numbers are appropriate for evaluation efforts (e.g., distinguishing sites needing intervention from those not needing intervention). The second reliability statistic is similar to traditional reliability estimates. For Proportion items, the reliability was .78 and site reliability was .50. For Duration items, the reliability was .79 and site reliability was .63. As with traditional internal consistency, the lower values for sites are likely due to the modest number of sites. This indicates adequate reliability of the MTFC-SIC, and that the measurement approach can make the distinctions necessary for evaluating implementation.

**FIT & MISFIT.** The model also provides information about “noisy” activities and sites (i.e., fit statistics). For Proportion items, there was no significant misfit for activities or sites. For Duration items, 4 activities and 4 sites were suggestive of misfit. Expert review determined that the misfitting sites were known to be sporadic in their implementation efforts, implementing various activities with little systematic progression. The misfitting activities were mandatory in nature, producing inconsistent “difficulty” estimates. This provides evidence that the SIC approach can be defined and implemented such that it performs in the manner expected.

**NESTING EFFECTS.** Nesting effects were evaluated for activities nested within stages that were nested within sites using Bernoulli and Poisson distributions. For proportion items, 64% of the total variance was due to items, 30% was due to stages, and 6% was due to sites. Of the stage variance, 82% was due to stage and 18% was due to site. For duration items, 83% of the stage variance was due to stage and 17% was due to site (item-level not estimated for Poisson models). This indicates that the SIC measure features of both stages and sites, the nesting effects are strong enough that they need to be addressed in the models, and the effects can be efficiently modeled using a multilevel Rasch model.

**LIMITATIONS & SUMMARY.** The primary limitation of the preliminary analyses is that the number of sites is modest and the content of the activities is specific to MTFC. The main strengths are that the SIC performs in expected ways, exhibits no fundamental measurement problems, and is efficiently expressed as a multilevel measurement model. Thus, nearly all evidence from evaluating the MTFC-SIC suggests that the implementation activities were effectively defined, the instrument behaves as intended, the Proportion and Duration scores are reliable and, despite the various measurement challenges, there are highly flexible methods for efficiently and effectively evaluating its performance. For the present proposal, this indicates that the SIC measurement approach has been successful for MTFC and is worthy of continued use; the investigative team can successfully lead efforts to extend the SIC to other EBPs; and the measurement methods required for evaluating the success of these efforts are readily available.

***PRELIMINARY ADAPTATION: COMPUTER-ASSISTED COPING CAT***

*To prepare for this resubmission, initial adaptation procedures for one of the participating EBPs were conducted to assess the viability of adapting the SIC for other EBPs, and the potential to identify consistent universal elements across them. The computer-assisted CC intervention was selected because it is the most disparate from MTFC. Meeting with the CC developers, the PI determined that each of the 8 SIC Stages were common among the EBPs, and 68% of items in the first 7 Stages were consistent with the MTFC-SIC. Stage 8 was not defined due to time and funding constraints. The item consistency within Stages varied from 100% to 50%. This initial step in the adaptation process indicates promise for the viability of the proposed project.*

**PROCEDURES**

Although the primary aims are to determine if the SIC can be applied across EBPs from different service sectors and accurately predict successful implementation outcomes, data provided from this project will allow investigation of EBP-specific implementation outcomes. Analyses will include examination of the impact that site demographic characteristics have on implementation behavior and cost outcomes. Moreover, because of the stage independence of the SIC, the varying impact of behavior in different stages will be evaluated.

**PARTICIPATING EVIDENCE-BASED PRACTICES**

Table 2 details the study timeline. The developers of three widely implemented EBPs from three public service sectors serving children and families have agreed to participate in the current project: Multisystemic Therapy (MST)<sup>8</sup> from the juvenile justice sector, Multidimensional Family Therapy (MDFT)<sup>9</sup> from the substance abuse sector, and a computerized version of Coping Cat (CC)<sup>10,11</sup> for the school setting. All three are recognized in the National Registry of Evidence-Based Programs and Practices ([www.nrepp.samhsa.gov](http://www.nrepp.samhsa.gov)) and, similar to MTFC, use an ecological approach to address clinical needs for children and families. MST and MDFT are intensive community-based interventions for serious externalizing behaviors, whereas CC is an office-based EBP for severe anxiety. Although there are many EBPs, the selection criteria for inclusion in this

study were: (a) EBP for child and family mental health within key service sectors (schools, juvenile justice, substance use) similar to the original model (MTFC for foster care); (b) Large real-world uptake within the respective service sectors in order to conduct study procedures; and (c) An established relationship with each of the EBP developers who have all expressed interest in using the SIC and in advancing understanding of the universal/common implementation elements shown to increase the successful uptake of EBPs.

The recruited EBPs all have a large implementation footprint for the service sectors in which they are adopted. MST purveyors have implemented MST in 38 states and 13 nations; MDFT has been implemented across 11 states and 6 countries; and CC has been implemented across the US and 3 countries. All three EBPs report a strong likelihood of continued growth. Last year, 27 programs adopted the computer-assisted version of CC, 67 programs MST, and 13 programs MDFT. As previously noted, other programs in additional service sectors have requested participation in developing a practice-specific SIC. This speaks to the appeal of the SIC to program developers and provides promise for recruiting a backup participating practice in the unlikely event that one of the three chosen EBPs fail to have newly adopting sites during the study period.

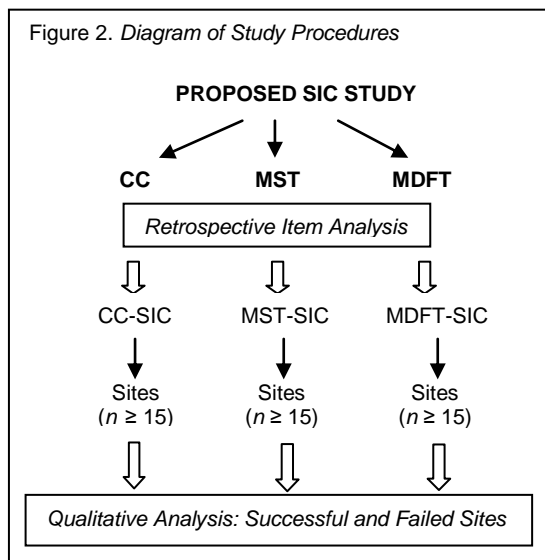
TABLE 2. PROJECT TIMELINE

Activity	Study Month									
	0-6	6-12	12-18	18-24	24-30	30-36	42-48	48-54	54-60	60-66
Database building	X	X	X							
Data management	X	X	X	X	X	X	X	X	X	X
CCAL SIC develop	X	X								
CCAL SIC evaluation	X	X	X	X	X	X	X	X	X	X
MST SIC develop		X	X							
MST SIC evaluation		X	X	X	X	X	X	X	X	X
MDFT SIC develop		X	X							
MDFT SIC evaluation			X	X	X	X	X	X	X	X
Qualitative Start-up	X									
Qualitative Assess		X	X	X	X	X	X	X	X	X
Advisory Board		X		X		X		X		X

**SPECIFIC AIM 1: ADAPTATION AND EXTENSION THROUGH RETROSPECTIVE AND PROSPECTIVE ANALYSIS**

Figure 2 provides a diagram of the overall study procedures. The start-up for each EBP will be rolled-out over the first year (Table 2). Taking advantage of an already funded implementation trial of CC in schools (in the start-up phase), development efforts will begin with CC. Next, the MST-SIC will be developed due to the

known complexity of the MST implementation process (the PI is a former MST researcher and consultant) and the anticipated longer length of time needed to accurately define this process. Finally, the MDFT-SIC will be developed with the knowledge that the developers continue to be highly involved in the implementation process and, therefore, have first-hand knowledge about most sites that have implemented their EBP.



An initial 1-day site visit will be conducted to each of the developer/purveyor organizations to learn about the standard implementation process for the EBP. The PI and developers will operationalize implementation activities and define completion criteria for these activities. EBP specific and universal/common activities within each stage will be mapped onto the SIC Stages.

**RETROSPECTIVE DATA MAPPING**

**MAPPING.** Each of the participating EBPs has agreed to provide data related to previous sites that have already implemented the EBP (see subaward details). Research assistants from each of the EBPs will be trained by the PI to code retrospective data related to

a minimum of 15 formerly implemented sites. Fifteen was selected as the number of sites because it balances time and other resource demands, is sufficient for observing variability in implementation activities, and is sufficient for conducting preliminary Rasch-based measurement models. Site names will be removed from all data prior to transferring to OSLC.

**MODIFICATION.** Based on initial examination of how well activities appear to define the stages, modifications will be made to each version of the SIC as needed. This might include moving activities from one stage to another, deleting activities, or redefining them. If substantive modifications are needed, an additional 15 sites will be coded retrospectively to verify that any modifications improve the measure's ability to accurately measure implementation. Analyses and recommendations for each EBP's SIC will be provided to the developer. Collaboratively, a final EBP specific SIC will be determined for use in prospective data collection.

## PROSPECTIVE DATA COLLECTION

Research staff at the EBP organizations (see consortium agreements) will be trained on data collection procedures for all newly adopting sites. A point person will be identified at each organization to monitor when new sites contact the purveyor to consider implementing the EBP (Stage 1) and to begin tracking the stage and activity data on the sites. The purveyors of each of the EBPs will be trained to note the completion of implementation activities by sites and the resources (both fees and person hours) needed to complete them. The trained data collection assistant will be responsible for gathering this information from the purveyors.

A weekly call will be conducted between EBPs and the investigative team (study PI and research economist). Data will be collected including (a) site demographics of all new sites (Table 3),<sup>34</sup> (b) completion of SIC activities, and (c) date of completion of SIC activities. Although data collection is based on observation by the purveyor of each site's completion of implementation activities, reliability of data collection still will be assessed. Within each purveyor organization, both the data collection assistant and the EBP site coordinator will independently record 10% of data. Data collected by phone between the EBP and the investigative team will be recorded on the SIC measure by both the PI and the research economist (i.e., 100% double coding).

## ANALYTIC PLAN

**SCORING.** Recalling that the implementation process is known to be nonlinear, the scoring of the SIC does not rely solely on chronological completion of activities or stages. It also does not assume that all sites will complete all activities in a stage or within a given timeframe. Each site will be given a stage Proportion score (percentage of activities completed in the stage), a stage Duration score (length of time between first and last completed activity in a stage, not necessarily chronologically), and a Stage score (the final stage attained).

**MEASUREMENT PROPERTIES.** Both retrospective and prospective data will be evaluated using IRT-based measurement models (i.e., dichotomous & Poisson Rasch models for activity completion and time-to-activity completion) and software (i.e., WINSTEPS, FACETS, HLM). Four sets of analyses will be conducted: (1) retrospective, (2) prospective, (3) combined retrospective and prospective, and (4) universal/combined across EBPs. To thoroughly assess the reliability and validity characteristics of each EBP-SIC version, the models will evaluate activity and site distributions, reliability, fit, variance components, and dimensionality (i.e., replication of methods described in preliminary studies).

A critical assumption is that item difficulty estimates are stable across uses of an instrument.<sup>35</sup> Thus, the activity estimates from retrospective data will be compared to those from prospective data, with stable estimates supporting the EBP-SIC versions. Invariance of activities "common" across EBPs will be evaluated. Assuming invariance, common item equating<sup>36</sup> will allow simultaneous calibration across EBPs. Multilevel formulations will provide activity, stage, and site estimates for each EBP. Likewise, an IRT-based item bifactor model<sup>37</sup> will provide loadings for each activity on its given stage and on a general implementation dimension.

**MISSING DATA.** There are two main types of missing data for the EBP-SIC versions due to an activity not being eligible for completion or not being applicable to an EBP. Importantly, the proposed models readily accommodate such missingness by efficiently and accurately estimating site and activity parameters.

**POWER.** For IRT models, statistical power refers to the precision of parameter estimates and SEs. Based on Linacre,<sup>38</sup> the smallest number of activities and sites (i.e., retrospective data) are sufficient for estimates accurate within  $\pm 1$  logit, with the prospective (and combined) data affording even greater precision. The combined data also are sufficient for accurate estimation of multilevel Rasch models.<sup>39</sup>

**IMPLEMENTATION PERFORMANCE: HYPOTHESIS TESTING.** Replicating procedures from the original MTFC implementation trial, agglomerative hierarchical clustering methods will be employed to find similarities within sites from each of the EBPs with regard to both Proportion and Duration scores for each stage. Sites will be clustered with regard to each of these variables independently, as well as together. Cox proportional hazard survival models then will be conducted with days-to-event (e.g., day of first youth served) as a time to event outcome for each of the three sets of clusters. The events analyzed will include significant milestones such as program start-up and certification. Additional significant events will be determined in collaboration with EBP developers in order to ensure that the SIC is able to accurately predict milestones that are identified as significant to the developers. It is hypothesized that each SIC version will produce outcomes similar to those found for MTFC such that both Proportion and Duration are significantly related to successful implementation outcomes.<sup>7</sup> The appropriate rate and necessary proportions might differ between EBPs and service sectors. *Universal items will be evaluated to determine if they are more critical than unique items for successful implementation.*

TABLE 3. SITE DEMOGRAPHICS

Site size
Population served
Funding type
Medicaid billing
Rural/Urban
Previous EBP Implementation
<i>Note.</i> Based on the Director's Survey (Schoenwald et al., 2003)

In the unlikely event that a minimum number of sites employ an EBP limiting the sample size for cluster and survival analyses, retrospective data will be used in combination with the prospective data. Given that a trained data collector will code retrospective data, there are limited risks to using retrospective data in this manner; however, retro versus prospective data will be included as a covariate to evaluate any differences.

## **SPECIFIC AIM 2: UNPACKING FAILED IMPLEMENTATION: EARLY DETECTION OF POTENTIAL FAILURE BY INCREASING UNDERSTANDING OF THE UNDERLYING SIC MECHANISMS**

### **ASSESSMENT OF SUCCESSFUL AND DISCONTINUED SITES**

**PARTICIPANTS.** *A random sample of sites from each EBP that discontinue the implementation process at any point from Engagement to Competency, or that successfully achieve competency, will be recruited for participation. Based on communication with developers about their previous experiences with new sites, we estimate that eight sites across EBPs will discontinue each year. Consenting sites will be asked to identify key individuals responsible for implementation decision making, ranging from system leaders to practitioners. Identified individuals will be asked to consent to participate in a one-time semi-structured qualitative interview or focus group regarding their experience of the implementation process, barriers that were experienced, and factors contributing to success or failure. The investigative team has experience engaging site leaders in research from the large-scale MTFC implementation trial. Participants will be compensated for their time. Consenting procedures will include a request for use of the sites' SIC data in relation to their identified data.*

**DEMOGRAPHICS AND POSITION CHARACTERISTICS.** Basic personal demographics (e.g., age, race, gender, education) will be assessed as will position characteristics (e.g., time in position, position level). Attempts will be made to include participants from each site that were involved in the implementation effort such that programs that discontinued early on in the implementation process might only have administrative-level participants, whereas programs that had undergone training might also have clinician-level participants.

**INTERVIEW.** Using an interview guide similar to those employed in previous studies of barriers and facilitators of EBP implementation,<sup>40,41</sup> qualitative interviews will be conducted by the PI and a trained qualitative research team under the guidance of Co-Investigator Palinkas. For sites that indicate that the decision to implement was informed by multiple agents, an on-site focus group will be conducted whereas those that report a single individual will be interviewed via video conferencing. Both are anticipated to last between 1 and 1.5 hr and will utilize techniques described in detail in Bernard<sup>42</sup> and Gilchrist<sup>43</sup> for interviews and Morgan<sup>44</sup> and Kreuger<sup>45</sup> for focus groups. Both will be digitally recorded and transcribed.

Participants will be asked a series of questions designed to elicit information on knowledge, attitudes and behavior related to the EBP, characteristics of the agency and team, characteristics of the external environment, and characteristics of the implementation process. However, the questions are also sufficiently open-ended to enable informants to elaborate on issues they consider important or relevant. For example, depending on how far they progressed in the implementation process, informants will be asked: (a) how they were involved in implementing the EBP; (b) what they know about the EBP philosophy and procedures; (c) how effective the planning process was in the pre-implementation phase (Stages 1-3) in preparing the organization for implementation, and what could have been done better; (d) how effective the training was in building skills in the EBP, and what could have been done better; (e) how effective the supervision was, and what could be done better; (f) whether they think the EBP would be helpful to the youth treated; (g) if it is a good idea for EBPs to be used in their agency; (h) whether the use of EBPs changed/would change their usual pattern of service delivery, and if so, how; (i) whether the EBP required changes in existing agency policies or procedures, and if so, how; (j) what costs and benefits were encountered in using the EBP; (k) how motivated the informant was; and (l) suggested changes for the EBP to have been successfully implemented.

### **ANALYTIC PLAN**

**QUALITATIVE ANALYSIS.** *As described by Co-Investigator Palinkas and colleagues (2011),<sup>53</sup> data from qualitative interviews and focus groups will be coded for analyses. Because thematic codes versus frequency of response will be included in analyses, both sets of data can be combined. Using a methodology of "Coding Consensus, Co-occurrence, and Comparison" outlined by Willms<sup>46</sup> and rooted in grounded theory (i.e., theory derived from data and then illustrated by characteristic examples of data),<sup>47</sup> interview and focus group transcripts will be analyzed in the following manner: First, investigators will prepare short descriptive "memos" to document initial impressions of topics and themes and their relationships and to define the boundaries of specific codes (i.e., the inclusion and exclusion criteria for assigning a specific code).<sup>48</sup> Then, the empirical material contained in the transcripts will be independently coded by the project investigators to condense the data into analyzable units. Segments of text ranging from a phrase to several paragraphs will be assigned codes based on a priori (i.e., from the interview guide) or emergent themes (also known as open coding).<sup>49</sup> Following the open-coding, codes will be assigned to describe connections between categories and between*

categories and subcategories (also known as axial coding).<sup>49</sup> Each text will be independently coded by at least two investigators. Disagreements in assignment or description of codes will be resolved through discussion between investigators and enhanced definition of codes. The final list of codes, constructed through a consensus of team members, will consist of a list of themes, issues, accounts of behaviors, and opinions that relate to implementation and fidelity. With the final coding structure, two investigators will separately review transcripts to determine the level of agreement in the codes applied. A level of agreement in the codes applied ranging from 66 to 97% depending on level of coding (general, intermediate, specific) indicates good reliability in qualitative research.<sup>50</sup> Based on these codes, the computer program QSR NVivo<sup>51</sup> will be used to generate a series of categories arranged in a tree-like structure connecting text segments grouped into separate categories or “nodes.” These nodes and trees will be used to examine the association between different *a priori* and emergent categories and to identify the existence of new, previously unrecognized categories. Finally, through the process of constantly comparing these categories with each other, the different categories will be further condensed into broad themes using a format that places implementation failures within the framework of the organizational and system characteristics.<sup>47</sup> The themes and their relationships to one another then will be organized to create a heuristic model of implementation process that can be used to develop and test hypotheses related to *underlying processes of the SIC*.

**MIXED METHODS ANALYSIS.** Data from discontinued sites’ SIC assessment, as well as their site characteristics will be examined in relation to qualitative outcomes to help increase understanding of *how site behavior, as defined on the SIC, relates to on-the-ground decision making*, using the mixed method technique of “convergence”.<sup>49,52,53</sup> This will allow for an assessment of the SIC’s utility in providing “early signal detection” of potential problems impeding successful implementation (*e.g., does longer duration in pre-implementation most often indicate that leadership does not have an accurate understanding of how to accomplish a key implementation activity?*). Thus, qualitative data will help to inform if there are reliable patterns of behaviors that are linked to particular patterns of SIC scores, thereby helping to unpack the potential for SIC scores to serve as a proxy for less easily observed phenomenon. Outcomes will be examined in the context of self-reported site characteristics to evaluate if these are related to SIC outcomes. In collaboration with Palinkas, the PI will summarize these two streams of data and determine the level of agreement between them.

### **SPECIFIC AIM 3: COSTS BY STAGE AND IMPLEMENTATION OUTCOMES**

#### **COST MAPPING UTILIZING THE SIC**

**DATA COLLECTION.** At the initial meeting with the PI and developers (SIC adaptation), an initial assessment of the effort, resources, and fees associated with each of the identified activities will be conducted, as perceived by the developer/purveyor. Then, throughout prospective data collection, during the calls between the EBP and the investigative team, data will be collected regarding the estimated person hours and resources used by sites to complete the SIC activities. In addition, information regarding ongoing, but not yet completed activities will be documented to help increase the accuracy of understanding the effort put into activity completion. For example, learning that a site has been working on their feasibility assessment for the last month and has sought consultation from the purveyor twice through email will be tracked despite the fact that the activity itself is not completed.

**ADDITIONAL COSTING PROCEDURES.** Although resources such as person hours and fixed fees will be identified through the previously described data collection calls, additional efforts will be necessary to cost implementation activities. Wherever possible, cost components such as wages and travel costs will be based on national average estimates in order to maximize the generalizability of the results and minimize the potential that performance sites are not typical with respect to salary structures. National public databases will be accessed to determine cost estimates for variables such as travel expenses, salaries, and meeting expenses for activities related to implementation. For example, we will use the Bureau of Labor Statistics’ wage and compensation data to measure hourly labor cost by job category.

#### **ANALYTIC PLAN**

**COST ESTIMATES.** There are three varieties of costs that must be measured within each stage of the SIC to evaluate the total cost of implementation. First, there is the direct cost of the implementation services to the site, which generally consists of the fees charged by the EBP purveyor. Second, the intervention will have indirect costs of site personnel time that is spent conducting the implementation (i.e., doing things that do not directly produce client services, and which will not be necessary once implementation is complete). Third, there are ancillary costs, which are made up of the actual infrastructure (and other) investments that are required for implementation, for example, the costs of acquiring and installing a new IT system for fidelity monitoring.

The direct costs will be straightforwardly measured as invoices from the EBP vendor to the site for services and support provided in each stage of the SIC. Indirect costs will be measured using a time/resource log (or

data collection tool) that we will design as part of the project. Each site and EBP will require a slightly different tool that will depend of the specific nature of the EBP, and will be generally based on personnel (i.e., therapists, secretary, project administration) and other costs that pertain to the EBP implementation, but not to the provision of clinical services to clients (or to the project costs for the research we will conduct). Included in personnel costs are base pay, fringe benefits, pro-rated hours in training, etc. We will collect units of cost (such as personnel time), and to the extent possible use national data (such as that collected by the Bureau of Labor Statistics) to generate the cost weights (prices or wages) for that time so that the estimated indirect costs will be representative of what a randomly selected program could expect, rather than dependent on the specific wage profiles of the sites participating in the study. Ancillary costs will be captured using a similar data collection tool as for the indirect costs; as with the indirect costs, the ancillary cost tool will need to be tailored to each EBP.

Costs of implementation will be expressed as average cost per SIC stage for each site. However, the raw average cost will not describe the range of possibilities. For example, a site that takes longer to move through a SIC stage will probably have a higher cost for that stage and merely including it in an average cost calculation would be misleading. Consequently, regression techniques will be used to estimate risk-adjusted cost functions, which can vary with such factors as the number of clients treated by a program or the time required to move through each stage of the SIC. The dependent variable of the regression will be logged implementation cost for each stage for each site. Ranges of costs will be imputed using the regression models, where staged implementation costs, and 95% confidence intervals for those costs, will be imputed by applying the Duan smearing estimate to predict the levels of SIC stage costs from the logged cost regression.

**IMPLEMENTATION PERFORMANCE AND COST.** The impact of behavior as rated on the SIC with regard to Proportion and Duration on cost and the need for resource allocation will be evaluated. Using regression models for each EBP, variations in cost will be examined as they relate to SIC scores. Presumably, the longer Duration scores will increase resource allocation needs, but perhaps not significantly. For example, in the MTFC trial it was found that although one implementation strategy was more expensive in terms of fees, the amount of time and effort was much less. The costs that are mapped onto activities will be calculated in relation to individual activities as well as stages. Cost curves will be estimated to help inform the optimal rate and Proportion of activity completion for sites to achieve success. It might be the case that sites that have higher initial costs (e.g., due to a high Duration) are more likely to have low Proportion scores during later stages (i.e., attempting to reduce implementation costs downstream). These variations will be considered in relation to successful achievement of implementation milestones.

#### **DISSEMINATION**

During the final year of study procedures for each EBP, developers will be collaboratively involved in determining the most beneficial uses of the SIC. All EBP specific outcomes will be shared and the way that the SIC operates for each EBP will be explained to the developers. For example, the original MTFC-SIC outcomes indicated that sites that linger too long in the pre-implementation phase (Stages 1-3) are less likely to achieve successful program start-up; the EBP developers/researchers might use this information to inform future modifications to their implementation process such as developing an enhanced protocol for struggling sites. Similarly, the developers/purveyors might determine that such information is important feedback for sites and develop strategies for conveying this information in a way that will help sites decide if it is in their best interest to proceed or not. In order for the EBPs to benefit from the SIC, a full understanding of the scoring methods, score meanings, and potential utility must be fully conveyed.

#### **ADVISORY BOARD**

Given the emerging field of measure development for implementation science, an Advisory Board of implementation experts has been recruited to help inform the development and evaluation of the SIC, barriers to successful implementation, and the assessment of implementation costs (Aarons, Snowden, Horwitz, Sosna, Marsenich; see letters of support). *The Board will include two additional experts who are end users: Young, the Director of Children and Family Futures, and the National Center on Substance Abuse and Child Welfare, and Pecora, the Research Director of the Casey Family Foundation.* Consultation will be sought by this Advisory Board throughout the SIC adaptation and evaluation process to seek input regarding implementation activity definitions *and the underlying processes captured by the SIC scores.* They will provide input on unpacking implementation failures *and successes* and understanding how implementation performance, as measured by the SIC, drives outcomes. Recommendations will be identified for intervention targets to help increase the potential success of sites that are at risk for failure and build hypotheses regarding the universal/common elements of successful implementation.

Annual advisory board meetings will be chaired by co-investigator Landsverk and conducted to provide updates to the group of study progress and to seek input on methods, analyses, and next steps. These

meetings will include all members of the investigative team including remote Co-Investigators. This group of experts also will collaborate on manuscripts and dissemination of study findings.

#### **INVESTIGATIVE TEAM**

The investigative team has a long history of collaboration and experience conducting research relevant to this application. The PI, Saldana, is an Early Stage minority investigator who has been an active Co-Investigator on the original MTFC implementation trial (R01MH076158; Chamberlain). In this role, she collaborated with Chamberlain in all aspects of running the study including research meetings, investigator meetings, analyses, study and design conceptualization, supervision of staff, and dissemination of study findings. As outlined in their biosketches, Chamberlain and Saldana have collaborated on a number of intervention trials and manuscripts. Saldana is in the 5<sup>th</sup> year of her K award (K23DA021603) on which Chamberlain serves as the primary mentor, and Co-Investigators Palinkas and Landsverk serve as consultants. Palinkas also collaborates with Saldana and Chamberlain on the MTFC implementation trial. Co-Investigator Bradford has collaborated with Saldana on studies related to health economics since 2005, when Saldana was a faculty scholar in Bradford's Center for Health Economics and Policy Studies at the Medical University of South Carolina. Since that time, Bradford has collaborated with Saldana and Chamberlain on service utilization data collection, cost analyses for intervention trials (R01DA024672; R01DA020172), and economic evaluation of the MTFC implementation trial. Palinkas, Landsverk, and Bradford have all helped in the development and conceptualization of the SIC. Co-Investigator Schoenwald serves as a consultant on the MTFC implementation trial, and also has collaborated separately with Bradford on economic evaluations of the MST model. Chapman, the analytic consultant on this project, collaborated with Saldana on conducting the psychometric analyses of the MTFC-SIC. He and Saldana have collaborated on additional analyses over the last 5 years, and he serves as Schoenwald's primary statistician for MST implementation and intervention studies. He is a member of Landsverk's analytic team for Landsverk's Advanced Center on implementation methods (P30MH074678), on which Saldana is an early career scientist, and Chamberlain, Schoenwald, and Palinkas are Co-Investigators. DeGarmo has served as a methodologist and analyst on grants (1R01DA020172; P30DA023920) and manuscripts with Chamberlain and Saldana.

The Advisory Board is comprised of implementation experts in children's mental health who also have a history of collaboration with the investigative team. Horwitz and Snowden serve on the Advisory Board for an OSLC Center grant (P30DA023920; Chamberlain) for which Saldana is an early career scientist. They also serve as consultants on Landsverk's implementation methods Center and attend annual meetings in this role. Sosna and Marsenich are the purveyors for the experimental implementation condition (CDT) for the MTFC implementation trial and assisted in data collection for the original MTFC-SIC. Aarons also is a Co-Investigator on Landsverk's Center and has published multiple manuscripts with members of the proposed team. He also is Saldana's primary mentor for the Implementation Research Institute (R25 MH080916; Proctor) on which he and Landsverk serve as Core faculty. She received this fellowship in addition to the NIH Training Institute for Dissemination and Implementation Research in Health in the summer of 2011.

#### **SUMMARY**

This proposal outlines a project that will extend the Stages of Implementation Completion to three EBPs serving children and families in three different service sectors. Data will be collected through retrospective and prospective procedures, qualitative interviews, and cost mapping strategies. Analyses will examine (1) the measurement properties of the EBP specific SIC measures; (2) the influence of pre-implementation, and early phase implementation performance on implementation milestone outcomes; (3) the perceptions of decision makers from *successful and unsuccessful* implementation sites as to what factors contributed to their decision to discontinue *or continue* implementation; (4) the *underlying implementation behaviors being captured by the SIC*; (5) the ability to use the SIC as a method of estimating implementation costs; and (6) the relationship between implementation performance and costs. At the end of the study period, each EBP will have access to their EBP-specific SIC measure for integration into their implementation and evaluation procedures.

Outcomes will help pave the way for future studies on the development of interventions to improve implementation approaches ultimately leading to more successful EBP implementations in child public service systems and increased availability of EBPs in usual care settings. This strong investigative team and Advisory Board have a history of collaboration and productivity in implementation research. Study findings will be used to help inform policy makers, community leaders, and other decision makers on what steps and resources are necessary for successful implementation efforts. This knowledge will help increase understanding of "what it takes" to install EBPs in real-world settings and, consequently, increase the availability of the most beneficial services to clients, and decrease wasted efforts and resources on failed implementation attempts.

## HUMAN SUBJECTS RESEARCH NARRATIVE

This proposal maps onto the NIH PAR-10-038 by targeting the “development of outcome measures and suitable methodologies for dissemination and implementation approaches that accurately assess the success of an approach to move evidence into practice.” The aims focus on developing a tool that could aid researchers, practices, and end users in assessing the process of implementing evidence-based programs into community settings, while simultaneously providing feedback and information to potential consumers with regard to implementation. The Stages of Implementation Completion (SIC), is an 8-stage measure developed to evaluate the implementation process for moving evidence-based practices into real-world settings. Data will be collected to achieve the following: (1) Adapt, generalize, and evaluate the SIC for three child and adolescent evidence-based practices that serve three different service sectors—juvenile justice, substance abuse, and school; (2) increase understanding of what barriers, contexts, and variables contribute to successful or failed implementation, and determine if the SIC can provide early detection of barriers that lead to potential implementation failure; and (3) measure the cost of implementation of each of the EBPs by using the SIC as a method for capturing implementation costs, and evaluate how implementation behavior as measured by the SIC is related to costs.

### HUMAN SUBJECTS INVOLVEMENT AND CHARACTERISTICS

The primary level of analysis for this study is related to implementation behavior (i.e., completion of activities and duration of time to complete them) of sites that implement one of three selected EBPs during the study period. The majority of the data collected for this study will be from the EBP purveyor organizations who track the steps sites go through while working toward implementing their respective EBP. Specifically, dates that the sites complete identified activities will be tracked by the EBP developer/purveyor and relayed to staff at OSLC. This data is strictly about when the site accomplishes key milestones and not about individuals. The sites will not be identified to OSLC (i.e., name of organization, geographic region, etc. will not be known).

However, when one of the sites either discontinues or successfully completes the implementation process, we will invite up to 5 site staff to participate in a one-time focus group to discuss their perceived barriers to implementation. Although we will invite up to 5 site staff to participate in the qualitative focus groups, we anticipate that on average, 3 staff will agree to participate. This figure was used for our targeted enrollment. Please note, however, that the level of participant that we are interested in studying is the number of *sites* who agree to provide information rather than the number of individuals. For sites that choose to have a single participant, an option will be given for a video conference interview. Prior to this invitation, the site first will sign a release of information allowing the purveyor organization to release their name and contact information to OSLC for recruitment.

### SOURCES OF MATERIALS

Data from human subjects will be collected through video recordings of small group discussions. Transcripts of the recordings will be analyzed.

### RECRUITMENT AND INFORMED CONSENT

Recruitment and informed consent will occur at two different levels for this study: (1) assessment of de-identified site implementation behavior as indicated by the date of completion of implementation activities, and (2) identified assessment of site members’ perceptions of contexts, facilitators, and barriers to successful implementation.

In collaboration with the purveyors of each of the three participating EBPs, in Years 1 thru 4, we will identify new sites consecutively that begin the implementation process with the purveyor. Together with the purveyor organizations, we will develop a passive consent process that will be initiated after sites contract with the purveyor (i.e., to ensure that the study does not interfere with a site’s decision of whether or not to engage with a particular purveyor). At that time, an informational letter will be sent to the administration of each site to inform them of the study and to inform them that identifying information will not be provided to OSLC study staff. The letter will, however, provide them with information outlining: (a) the voluntary nature of participation, (b) the right to withdraw from the study at any time, (c) the purpose of the study and how the data will be used, (d) the types of data to be collected, (e) an explanation of confidentiality and the exceptions to it, (f) possible risks to the organization, (g) potential benefits to the organization, and (h) contact information if they have questions or concerns regarding the procedures. The organization will be asked to reply if they want to opt out of the study. No response will be considered consent for the EBP purveyor organization to provide OSLC with data about the site and their implementation behavior. As part of recruitment tracking, we will ask the purveyor organization to let us know the number of sites that do choose to opt out of data tracking so that we are able to calculate a participation rate.

For sites that either discontinue or successfully complete the implementation process with a purveyor, a release of information will be sought allowing the purveyor to release the site name and contact information to



OSLC. At this time, the Project Coordinator will contact the site administrator and invite them and up to four additional staff or stakeholders to participate in a focus group. Individuals who were involved in the decision making regarding the implementation process will be sought. An individual interview will be conducted when only one person from the site agrees to participate; otherwise, qualitative data will be collected in the form of focus groups. At the beginning of the focus group or individual interview, participants will sign a brief consent form that outlines: (a) the voluntary nature of participation, (b) the right to withdraw from the focus group at any time, (c) the purpose of the focus group and how the data will be used, (d) the types of data to be collected, (e) an explanation of confidentiality and the exceptions to it, (f) possible risks to the participants, (g) potential benefits to the participants, and (h) contact information if they have questions or concerns regarding the assessment procedures. Participants will be given a copy of the consent form.

### **POTENTIAL RISKS**

Potential discomforts and risks of participating in this study include possible:

- (1) feelings of coercion about consenting to participate in the study,
- (2) misunderstanding regarding the use to which the data will be put,
- (3) violation of confidentiality, and
- (4) dissatisfaction with the focus group procedures.

### **PROTECTION AGAINST RISK**

As a general protection against the human subject risks, all OSLC staff will go through Human Subjects training including reading general information about the human subjects' protections such as the Belmont Report and watching an OSLC-developed presentation. These trainings are required by all OSLC scientists and staff prior to receiving access to any confidential information in hard copy files or access to databases. In addition, all key personnel are required to take the NIH Office of Extramural Research (OER) "Protecting Human Research Participants" online tutorial whereby a certificate is issued by NIH upon completion. Staff collecting site/provider organization data at the three EBP partner sites (see consortium agreements) also will either complete the NIH online tutorial or provide documentation of completion of an equivalent training.

#### **POTENTIAL RISKS #1 (FEELING COERCED TO CONSENT) & #2 (MISUNDERSTANDING OF DATA USE):**

**SAFEGUARDS.** As described in the Recruitment and Informed Consent section above, new sites for each EBP will be provided with a detailed passive consent document outlining that data will be collected with regard to the date that they complete their implementation activities. For focus groups, all participants will be required to read and sign a detailed consent form before participating in the focus groups. In addition to explaining assessment procedures, uses to which the data will be put, and confidentiality of the data, both consent forms stress the voluntary nature of participation and the right to withdraw from the study at any time. The PI (Saldana) and research staff are available at all points of the study to answer questions and to explain assessment procedures and uses to which the data will be put.

In addition to verbally explaining all consents, we use readability indexes to adjust the reading level required for our consent forms.

**POTENTIAL RISK #3 (VIOLATION OF CONFIDENTIALITY): SAFEGUARDS.** All OSLC and partner EBP staff and volunteers sign confidentiality agreements. No one other than OSLC study staff will have access at any time to records identifying subjects' names. The data collected during the focus groups are unlikely to be personal or sensitive in nature, however we will adhere to all confidentiality procedures as if it were. Implementation process data collected on sites from purveyor organizations will be provided in a de-identified format. The information gathered will be used only for scientific, educational, or instructional purposes.

As noted, it is unlikely that we will receive information regarding harm to individuals that may require reporting to authorities; however, all existing procedures to prevent the violation of confidentiality, in accordance with state law reporting requirements, are limited by the mandatory nature of these requirements. Subjects are informed in the consent documents and procedures that staff must report to authorities (a) physical injury to any child caused by other-than-accidental means, as required by state statutes, and (b) information from a study participant that leads staff to believe a person is in imminent danger of physical harm. Staff will also inform parents or guardians if, in the judgment of the professional staff, their child (under 18) is in imminent danger of attempting suicide.

To ensure confidentiality, all information will be coded so that it cannot be associated with any individual's name. Identifying information needed for site or participant contact, such as names, addresses, and telephone numbers will be kept in locked file cabinets or in our secure subject database. Access to the subject database on the OSLC network is further protected, being restricted to only those staff members whose jobs require this information for subject contact. These individuals require an additional (and different) username and password. Individual network and database passwords will be changed regularly. All staff members are trained to close password-protected applications or lock their workstations when they are away from their desks.

All hard copy and electronic data are stored in secure storage, either locked cabinets (OSLC) or restricted areas on computer networks (OSLC). The OSLC computing systems are protected from outside access by firewall systems. The planned complexity of these systems helps increase the security of the local networks. Servers maintain logs and generate reports of access attempts, which are reviewed by the Network Administrator.

Access to OSLC buildings and offices are restricted. Reception staff supervise public entrance during normal operating hours. All space accessible to the public is separated from research offices by locked, coded doors. All staff entrances are secured with locked, coded doors. Staff entry codes are changed regularly.

During data analysis, all identifying information with the exception of the subject identification number is removed. No information about the identities of study participants will be published or presented at conferences.

**POTENTIAL RISK #4 (DISSATISFACTION WITH PROCEDURES): SAFEGUARDS.** Prior to the focus group, participants are reminded that they may choose to skip any question or procedure they find uncomfortable and that they have the right to leave the focus group at any time.

The PI and Project Coordinator have considerable experience in conducting focus groups and have undergone previous training to facilitate the groups. To prevent discomfort or embarrassment, staff will undergo ongoing training in non-judgmental and supportive facilitation techniques.

During their participation in the study, EBP sites may have questions about the study. Participants will be encouraged to discuss with the project PIs and coordinators any possible dissatisfaction with assessment activities. Experienced research staff members are available at all points of the study process to answer questions and to explain assessment procedures, uses to which the data will be put, and confidentiality of data. An independent ombudsman is also available should a participant not wish to discuss a grievance with OSLC (related to the study). All grievance procedures are made available to participants both orally and in writing during the informed consent procedures.

The risks to subjects are reasonable given the goals of the study:

- (1) Based on our experience, the procedures cause little, if any, discomfort. In fact, in our similar studies, participants have reported that they enjoy being in the study and routinely agree to participate in repeated assessments.
- (2) The participants will be compensated for their time and expenses and will receive full and timely debriefing.
- (3) Although participants from sites who discontinue the implementation process might feel discomfort from acknowledging their unsuccessful implementation attempt, the focus group will allow them the opportunity to openly discuss challenges they experienced and contribute to our learning of how to help increase the effectiveness of implementation processes for the future.

#### **IMPORTANCE OF THE KNOWLEDGE TO BE GAINED**

Outcomes from this study have the potential to be highly significant to the field of implementation science. This project will culminate in a standardized and generalizable measure of implementation processes and their associated costs. Having such a measure will aid researchers in their ability to continue investigating theories and frameworks of implementation. This measure also will help developers and purveyors provide informed guidance to newly adopting sites on their implementation performance in order to increase their potential for success. Further, by examining the perceived barriers to successful implementation of non-successful sites in conjunction with data provided by the SIC measure, we will determine if the SIC can accurately predict early signs of implementation failure. Such knowledge will allow for implementation interventions to help support the faltering sites.

Ultimately the knowledge gained from this study will help close the research-to-practice gap by providing measurable means for evaluating implementation of evidence-based practices. Such measures are essential for continuing to develop and evaluate implementation strategies in order to increase the availability of evidence-based practices in real-world community settings.

#### **COLLABORATING SITE(S):**

Oregon Social Learning Center  
10 Shelton McMurfhey Blvd.  
Eugene, Oregon 97401  
OHRP Assurance Number: FWA00005440

University of Miami

Sponsored Programs  
PO Box 025405  
Miami, FL 33102-5405  
OHRP Assurance Number: FWA00002247

MST Services  
710 J Dodds Blvd., Suite 200  
Mt. Pleasant, SC 29464

CAADC at Temple University  
1701 N. 13th St.  
Philadelphia, PA 19122-6011  
OHRP Assurance Number: FWA00004964

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